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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,876	12/12/2003	Howard T. Bellin	2003-2090.CON	1026
23165	7590	06/07/2006	EXAMINER	
ROBERT J JACOBSON PA 650 BRIMHALL STREET SOUTH ST PAUL, MN 551161511			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/734,876

Applicant(s)

BELLIN ET AL.

Examiner

Bruce E. Snow

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21, 23, 26, 28, 30, 33 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 23, 26, 28, 30, 33, 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____                                                            | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Response to Arguments*

Applicant's amendments and arguments filed 3/20/06 have been fully considered.

The rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in response to applicant's deletion of the indicated language.

The rejection under 35 U.S.C. 102(b) as being anticipated by McGhan et al (3,852,832) was withdrawn due to applicant's addition of the language "*wherein the envelope includes an opening through which a mandrel has been removed.. wherein the envelope apart from said patch is one-piece*". In the parent application, this language according to the Examiner's supervisors in an appeal conference, made the claims allowable because the patch of McGhan et al is needed to make the envelope both thicker and relatively rough on the posterior surface.

Regarding the Prescott (5,522,896) reference, one skilled in the art clearly understands how a "conventional prosthesis such as a conventional silicone breast prosthesis (column 5, lines 59-60)" can be filled with a fluid. **One of ordinary skill in the art of breast prostheses interpreting said reference would deem this to be inherent.**

Inherently, a conventional prosthetic with an additionally coating, such as the breast implant in figure 1B, would be thicker. Prescott teaches coating a single posterior side in figure 1b and in column 5, lines 53-54. The rejection under 35 U.S.C. 102(b) as

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being anticipated by Prescott (5,522,896) has been withdrawn due to applicant amendments including "wherein the envelope is sealed with a patch".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23, 26, 28, 30, 33, 35-46 (all claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Prescott (5,522,896) in view of Baker (5,026,394).

Referring to figure 1B, Prescott teaches a breast implant comprising an envelope (conventional prosthetic device) and adding an additionally layer/coating 4 on said envelope. Prescott teaches:

*"The prosthesis of the present invention can also comprise a base material of predetermined shape, e.g., a conventional prosthetic device, and a layer of elastomeric material provided on the base material, wherein the layer of elastomeric material has distributed therein or provided thereon bio-active ceramic or glass particles (column 5, lines 34-39)" and the "(column 5, lines 59-60)" conventional prosthesis such as a conventional silicone breast prosthesis*

Inherently, a conventional prosthetic with an additionally coating, such as the breast implant such in figure 1b, would produce a thicker posterior side relative to the anterior side. It is noted that Prescott teaches the coating to increase tissue adhesion; see at least column 1, lines 29-38. The posterior surface with coating is relatively rough when compared with the anterior surface without a coating.

However, Prescott is silent regarding a patch. Baker teaches a "convention breast prosthesis" which includes a patch 34 covering an opening. Also note Baker teaches a thicker posterior. It would have been obvious to one having ordinary skill in the art to have utilized the prosthesis of Baker which is has an opening sealable with a patch such that the envelope could be easily and cheaply manufactured on a mandrel (see 3:65 of Baker) or allow for an opening for the reinforcing members to be inserted.

Reversely, it would have been obvious to one having ordinary skill in the art to have utilized the posterior coating of Prescott (see figure 1b) on the breast prosthesis of Baker to better anchor said prosthesis; see at least 1:24 et seq. of Prescott.

Lacking any criticality in the specification, the use of the claimed thicknesses lacks criticality in the specification and solves no stated problem and would have been an obvious matter of design choice within the skill of the art. Additionally, it would have been obvious to one having ordinary skill in the to adjusted the thickness of both sides of the implant to adjust flexibility and/or increase strength.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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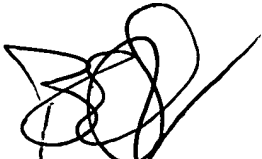
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BRUCE SNOW  
PRIMARY EXAMINER